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Opening Statement
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Chairman Dan Burton

Committee on Government Reform

"FACA: Conflicts of Interest and Vaccine Development:

Preserving the Integrity of the Process"

Thursday, June 15, 2000

1:00 pm

2154 Rayburn House Office Building

Washington, DC 20515

Today, we are going to continue our series of hearings on vaccine policy. For the last few months, we've been focusing on two important advisory committees. The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) rely on these advisory committees to help them make vaccine policies that affect every child in this country. We've looked very carefully at conflicts of interest. We've taken a good hard look at whether the pharmaceutical industry has too much influence over these committees. From the evidence we found, I think they do.

The first committee is the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). This Committee makes recommendations on whether new vaccines should be licensed. The second committee is the CDC's Advisory Committee on Immunizations Practices (ACIP). This committee recommends which vaccines should be included on the Childhood Immunization Schedule.

To make these issues easier to understand, we're going to focus on one issue handled by these two committees - the Rotavirus vaccine. It was approved for use by the FDA in August 1998. It was recommended for universal use by the CDC in March 1999. Serious problems cropped up shortly after it was introduced. Children started developing serious bowel obstructions. The vaccine was pulled from the U.S. market in October 1999.

So the question is, was there evidence to indicate that the vaccine was not

safe and if so, why was it licensed in the first place? How good a job did the advisory committees do? We've reviewed the minutes of the meetings. At the FDA's committee, there were discussions about adverse events. They were aware of potential problems. Five children out of 10,000 developed bowel obstructions. There were also concerns about children failing to thrive and developing high fevers, which as we know from other vaccine hearings, can lead to brain injury. Even with all of these concerns, the committee voted unanimously to approve it.

At the CDC's committee, there was a lot of discussion about whether the benefits of the vaccine really justified the costs. Even though the cost-benefit ratio was questioned, the Committee voted unanimously to approve it.

Were they vigilant enough? Were they influenced by the pharmaceutical industry? Was there appropriate balance of expertise and perspectives on vaccine issues? We've been reviewing their financial disclosure statements. We've interviewed staff from the FDA and the CDC. The staff has prepared a staff report summarizing what we've found. At the end of my statement, I'll ask unanimous consent to enter this report into the record. We've identified a number of problems that need to be brought to light and discussed.

Families need to have confidence that the vaccines that their children take are safe, effective, and truly necessary. Doctors need to feel confident that when the FDA licenses a drug, that it is really safe, and that the pharmaceutical industry has not influenced the decision-making process. Doctors place trust in the FDA and assume that if the FDA has licensed a drug, it's safe to use. Has that trust been violated?

How confident in the safety and need for specific vaccines would doctors and parents be if they learned the following:

1. That members, including the Chair, of the FDA and CDC advisory committees who make these decisions own stock in drug companies that make vaccines.

2. That individuals on both advisory committees own patents for vaccines under consideration or affected by the decisions of the committee.

3. That three out of five of the members of the FDA's advisory committee who voted for the rotavirus vaccine had conflicts of interest that were waived.

4. That seven individuals of the 15 member FDA advisory committee were not present at the meeting, two others were excluded from the

vote, and the remaining five were joined by five temporary voting members who all voted to license the product.

5. That the CDC grants conflict-of-interest waivers to every member of their advisory committee a year at a time, and allows full participation in the discussions leading up to a vote by every member, whether they have a financial stake in the decision or not.

6. That the CDC's advisory committee has no public members - no parents have a vote in whether or not a vaccine belongs on the childhood immunization schedule. The FDA's committee only has one public member.

These are just a few of the problems we found. Specific examples of this include:

Dr. John Modlin-He served for four years on the CDC advisory committee and became the Chair in February 1998. He participated in the FDA's committee as well owned stock in Merck, one of the largest manufacturers of vaccines, valued at $26,000. He also serves on Merck's Immunization Advisory Board. Dr. Modlin was the Chairman of the Rotavirus working group. He voted yes on eight different matters pertaining to the ACIP's rotavirus statement, including recommending for routine use and for inclusion in the Vaccines for Children program. It was not until this past year, that Dr. Modlin decided to divest himself of his vaccine manufacturer stock.

At our April 6 autism hearing, Dr. Paul Offit disclosed that he holds a patent on a rotavirus vaccine and receives grant money from Merck to develop this vaccine. He also disclosed that he is paid by the pharmaceutical industry to travel around the country and teach doctors that vaccines are safe. Dr. Offit is a member of the CDC's advisory committee and voted on three rotavirus issues - including making the recommendation of adding the rotavirus vaccine to the Vaccines for Children's program.

Dr. Patricia Ferrieri, during her tenure as Chair of the FDA's advisory committee, owned stock in Merck valued at $20,000 and was granted a full waiver.

Dr. Neal Halsey, who serves as a liaison member to the CDC committee on behalf of the American Association of Pediatrics, and as a consultant to the FDA's committee, has extensive ties to the pharmaceutical industry, including having solicited and received start up funds from industry for his Vaccine Center. As a liaison member to the CDC committee, Dr. Halsey is there to represent the opinions of the organization he represents, but was found in the transcripts to be offering his personal opinion as well.

Dr. Harry Greenberg, who serves as Chair of the FDA committee, owns

$120,000 of stock in Aviron, a vaccine manufacturer. He also is a paid member of the board of advisors of Chiron, another vaccine manufacturer and owns $40,000 of stock. This stock ownership was deemed not to be a conflict and a waiver was granted. To the FDA's credit, he was excluded from the rotavirus discussion because he holds the patent on the rotashield vaccine.

How confident can we be in the process when we learned that most of the work of the CDC advisory committee is done in "working groups" that meet behind closed doors, out of the public eye? Members who can't vote in the full committee because of conflicts of interest are allowed to work on the same issues in working groups, and there is no public scrutiny. I was appalled to learn that at least six of the ten individuals who participated in the working group for the rotavirus vaccine had financial ties to pharmaceutical companies developing rotavirus vaccines.

How confident can we be in the recommendations with the Food and Drug Administration when the chairman and other individuals on their advisory committee own stock in major manufacturers of vaccines?

How confident can we be in a system when the agency seems to feel that the number of experts is so few that everyone has a conflict and thus waivers must be granted. It almost appears that there is a "old boys network" of vaccine advisors that rotate between the CDC and FDA - at times serving simultaneously. Some of these individuals serve for more than four years. We found one instance where an individual served for sixteen years continually on the CDC committee. With over 700,000 physicians in this country, how can one person be so indispensable that they stay on a committee for 11 years?

It is important to determine if the Department of Health and Human Services has become complacent in their implementation of the legal requirements on conflicts of interest and committee management. If the law is too loose, we need to change it. If the agencies aren't doing their job, they need to be held accountable. That's the purpose of this hearing, to try to determine what needs to be done.

Why is this review necessary? Vaccines are the only substances that a government agency mandates a United States citizen receive. State governments have the authority to mandate vaccines be given to children prior to admission to day care centers and schools. State governments rely
on the recommendations of the CDC and the FDA to determine the type and schedule of vaccines.

I am not alone in my concern about the increasing influence of

industry on medicine. Last year, the New England Journal of Medicine learned that 18 individuals who wrote drug therapy review articles had financial ties to the manufacturer of the drugs discussed. The Journal, which has the most stringent conflict of interest disclosures of medical journals, had a recent editorial discussing the increasing level of academic research funded by the industry. The editor stated, "What is at issue is not whether researchers can be 'bought' in the sense of a quid pro quo, it is that close and remunerative collaboration with a company naturally creates goodwill on the part of researchers and the hope that the largesse will continue. This attitude can subtly influence scientific judgment."

Can the FDA and the CDC really believe that scientists are more immune to self-interest than other people?

Maintaining the highest level of integrity over the entire spectrum of vaccine development and implementation is essential. The Department of Health and Human Services has a responsibility to the American public to ensure the integrity of this process by working diligently to appoint individuals that are totally without financial ties to the vaccine industry to serve on these and all vaccine-related panels.

No individual who stands to gain financially from the decisions regarding vaccines that may be mandated for use should be participating in the discussion or policy making for vaccines. We have repeatedly heard in our hearings that vaccines are safe and needed to protect the public. If the panels that have made the decisions on all vaccines on the Childhood Immunization Schedule had as many conflicts as we found with rotavirus, then the entire process has been polluted and the public trust has been violated. I intend to find out if the individuals who have made these recommendations that effect every child in this country and around the world, stood to gain financially and professionally from the decisions of the committees they served on.

The hearing record will remain open until June 28 for those who would like to submit a statement into the hearing record.

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